Return Application With Check Payable To:
Treasurer – State of NH
Application Fee: $250

State of New Hampshire
Board of Pharmacy
121 South Fruit Street
Concord, NH 03301-2412
Tel.: (603) 271-2350 Fax: (603) 271-2856
Website: www.nh.gov/pharmacy/

Board Use Only

JULY 1, 2015 TO JUNE 30, 2016 LICENSING PERIOD

APPLICATION FOR PERMIT - BULK STERILE & NON-STERILE COMPOUNDERS
(Including FDA Registered 503B Outsourcing Facilities)
Shipping Non-Patient Specific / Bulk Compounded Products to New Hampshire

Name & Location Of Bulk Compounding Facility:

Company Name:_____

Street Address: _____

City / State / Zip:_____

Parent Company (If none, write 'None'):	State Of Incorporation (If Corp.):
Telephone:	E-Mail Address:
DEA Number (If Shipping Controlled Drugs):	State Controlled Substance Lic. #, If Applicable:

Name of Owner(s): Indicate Individual, Partners, Etc. (If Corporation, Show Title of Officers). Attach Additional Sheet If Necessary.

Name	Address	Title
Name	Address	Title

Is your company licensed by the board of pharmacy in the state of location? ❑ Yes * ❑ No **

** If 'Yes', you must attach a copy of your current home-state license to this application.*

** If 'No', you must attach an explanation as to why a license is not required in your home-state.*

Is your company registered as a 503B Outsourcing Facility by the FDA? ❑ Yes ❑ No

Has your company been inspected by the FDA? ❑ Yes ❑ No

If inspected by the FDA, was your company issued a 483 ? ❑ Yes * ❑ No

*If yes, attach a copy of the FDA Form 483, along with your company's response to the issues noted on the 483.

Within the last 5-years, has a registration or licensure granted to the above referenced company by any state or federal agency been suspended, revoked, or otherwise disciplined? ❑ Yes * ❑ No ** (If "Yes", attach a detailed explanation, along with copy of legal documentation of discipline)*

Provide the name, title, & business mailing address of the person to whom the permit, future renewal applications, and all Board communications should be directed:

Name:	**Title:**	**Tel. #:**
Mailing Address:		
E-Mail Address:		

APPLICATION CONTINUED ON NEXT PAGE ↳

If also shipping controlled drugs, provide the name, telephone/fax #, email, & mailing address of the person to whom communication regarding controlled substance distribution records may be directed (a copy of your company's DEA permit must also be attached) :

Name: Telephone #: Fax #: E-Mail:

Business Mailing Address:

Which of the following entities do you sell / ship to? (Check All That Apply)

❑ Retail Pharmacies ❑ Hospital Pharmacies ❑ Licensed Clinics / Surgical Centers ❑ Practitioners (MD, DMD, DVM, APRN, PA-C)

❑ Other (List):_____

Attachments & Declaration / Signature By Company Representative:

I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. I understand that as an outsource facility I am required to comply with current Good Manufacturing Practice (cGMP) standards. I have read and understand the testing requirements required for shipping compounded products into New Hampshire.

1. All High Risk products compounded from bulk non-sterile active pharmaceutical ingredients (API) must be tested to ensure the products meet final product specifications before the products are shipped to NH providers. No products shall be released for use until this testing is conducted and the results confirm that the finished drug meets specifications. Copies of the test results shall be included with each batch sent to New Hampshire practitioners and must be available for inspection by the pharmacy board.

2. Low – Medium Risk compounded drug products from sterile, commercially available raw materials shall confirm sterility through process control validated by testing of at least 20 percent of the lots of each product shipped into New Hampshire. Results of these tests shall be provided to New Hampshire customers in receipt of the compounded preparations and available for inspection by the pharmacy board.

Attachments Required:

☐ **1. If shipping controlled drugs, attach a copy of the facility's current DEA Registration Certificate;**

☐ **2. If licensed by your home-state, attach a copy of your current home-state license.**

☐ **3. If inspected by the FDA and issued a Form 483, attach a copy along with a copy of your company's response.**

Signature: _____ Title: _____ Date: _____

INCOMPLETE APPLICATIONS OR APPLICATIONS WITHOUT REQUIRED ATTACHMENTS WILL NOT BE ACCEPTED.

DO NOT LEAVE ANY BLANK SPACES – IF NOT APPLICABLE, WRITE N/A & THE REASON IT DOES NOT APPLY.

Any Subsequent Changes To The Information On This Form Must Be Reported To The Board In Writing Within 30 Days.